

**Division of Kidney, Urologic and  
Hematologic Diseases**

**Josephine P. Briggs, M.D.  
Director**

**September 2002 Council**

## **Division of Kidney, Urologic and Hematologic Diseases**

### **Table of Contents**

#### **Initiatives**

Trial of Intensive Dialysis in Acute Renal Failure	1
Daily Dialysis Randomized Control Trials (RFA DK-02-012)	2
Red Blood Cell Genomics	3
Transmission of HIV in Semen	4
Initiative to Develop MRI Technology for Assessment of Iron	5
Basic Research Studies on Biology of the Bladder	6
Chronic Prostatitis Collaborative Research Network (DK-03-004)	7
Cell Type Tools for Prostate and Bladder (PAR-02-143)	9
Daily Dialysis Registry	10
Interstitial Cystitis Clinical Trials Network (RFA DK-03-003)	11
Basic Research Studies on Interstitial Cystitis	12

<b>Conferences and Workshops</b>	<b>13</b>
----------------------------------	-----------

## **TRIAL OF INTENSIVE DIALYSIS IN ACUTE RENAL FAILURE**

### **FY 2003 Action**

It is planned to embark on a collaborative initiative together with the VA to fund a clinical trial to study whether intensive dialysis offers benefit to patients with acute renal failure (ARF).

### **Background**

Patients with acute renal failure who require dialysis have a mortality rate of about 50 percent. The amount of dialysis needed and the best mode of dialysis therapy are all unknown, although a recent randomized trial suggested that increased dialysis may improve survival. There is strong interest in the renal community for a trial that tests if intensified dialysis in patients with ARF improves outcome. The VA Cooperative Trials Office is considering a trial of intensive dialysis (high dose, daily, early start) *versus* conventional dialysis, but needs access to additional patients to achieve adequate statistical power. We propose to undertake a collaborative study under joint sponsorship. The VA would pay for the DCC and about one half of the enrolled patients. NIH funded investigators in centers with VA collaborations would be established, and NIH support provided for study goals and potentially ancillary studies.

### **Research Goals and Scope**

A randomized clinical trial to be implemented in a consortium of VA and non-VA sites will be undertaken. The trial will compare the impact of standard care *versus* early and intensive dialysis on patient mortality, length of hospitalization and other morbidity. A joint oversight mechanism with the VA and the NIH will be established.

## **DAILY DIALYSIS RANDOMIZED CONTROL TRIALS (RFA DK-02-012)**

### **FY 2003 Action**

It is proposed to invite cooperative agreement applications for a Data and Analysis Coordinating Center (DACC) and two Coordinating Clinical Centers (CCCs) to design, develop and implement clinical treatment trials of frequent hemodialysis for patients with end stage renal disease (ESRD).

### **Background**

End stage renal disease afflicts approximately 380,000 Americans. Most are receiving hemodialysis three times per week. This frequency of hemodialysis, while conventional and capable of sustaining life, has no solid scientific basis. Although this schedule is compatible with prolonged survival for some patients, the annual mortality rates are quite high for the entire population of ESRD patients. More frequent hemodialysis has been employed by some centers in small numbers of selected patients. The modalities have included home and in-center hemodialysis delivered four to seven times per week with standard blood and dialysate flow rates. Some centers have employed a day time therapy of shorter duration per dialysis session than with the thrice weekly schedule. Alternatively, in the nocturnal version, lower than standard flow rates have been used but for longer periods of time than the usual, often 8 hours per night. The results of these approaches to increased frequency have been reportedly good. Reductions in blood pressure, serum phosphate levels and erythropoietin requirements have been noted. Improved patient well being has also been reported. However, these observations are derived from small groups of selected patients in a few centers. Large numbers of subjects (N = 1,000 or more) are generally required to assess the effect of any change in ESRD therapy on mortality and cardiovascular events, e.g. stroke, myocardial infarction and heart failure, all of which often complicate ESRD. Based on previous studies of small numbers of daily dialysis patients, and the uncertain ability to randomize patients into daily *versus* conventional frequency, the trials conducted under this RFA will focus on intermediate outcomes. These outcomes include blood pressure, left ventricular hypertrophy, nutritional status, anemia, quality of life, and vascular access.

### **Research Goals and Scope**

The DACC and CCCs will propose trial designs for the studies. It is anticipated that two trials will be initiated, one comparing short daily hemodialysis with conventional dialysis and one comparing long nocturnal dialysis with conventional dialysis. The goals are (1) to test the feasibility of randomizing a representative sample of dialysis patients into either conventional three times per week dialysis, or one of the two forms of frequent dialysis named above; and (2) to obtain preliminary data on the impact of these modalities on patient well-being. It is expected that patients will be followed for a minimum of six months and that intermediate outcomes (anemia, nutritional status, blood pressure, left ventricular hypertrophy, exercise tolerance, medication use, hospitalizations, etc.) will be tracked. Based on the results of these trials, NIDDK will determine the advisability of continuing with a large scale trial of daily dialysis, powered to measure the impact of frequent dialysis on hard endpoints, such as mortality and/or cardiovascular outcomes.

## **RED BLOOD CELL GENOMICS**

### **FY 2003 Action**

The goal of this initiative is to create a consortium to characterize the process of erythroid differentiation at a molecular level.

### **Background**

This initiative is based on a workshop held on December 19-20, 2001, that brought together experts from red cell biology and functional genomics. The relatively simple gene expression profile of erythroid cells as they terminally differentiate provides a useful biological system in which to study functional genomics. The ability to obtain purified cells at various stages of differentiation makes the erythroid system uniquely accessible. During the last cell cycle of erythropoiesis and just before nuclear extrusion from the reticulocyte, only approximately 1,000 genes are actively transcribed. Some of these genes have been identified using protein purification strategies, followed by isolation of particular cDNAs that could be subsequently used as probes. Others have been genetically characterized, either through the use of mutants or by positional cloning. And still others are currently unidentified. It now seems feasible to catalog the total subset of genes that are expressed during erythropoiesis and to determine the time course of gene expression.

This biological system provides an opportunity to develop and refine the strategies of computational biology and the analytic tools being developed for study of complex systems. Improved computational techniques can be developed and assessed if complete data sets about the expression of a well-defined subset of genes are available. The use of such a characterized subset of genes will allow computational biological methods to be more finely tuned, with the long-term goal of full understanding of terminal erythroid cell differentiation.

### **Research Goals and Scope**

The purpose of this initiative is to merge the two fields of red cell biology and computational biology to advance our knowledge of red blood cell biology. Proposals will be invited that utilize state-of-the-art, functional genomics tools. In addition applicants will be encouraged to develop computational models that may be used in other tissue or organ systems.

## **TRANSMISSION OF HIV IN SEMEN**

### **FY 2003 Action**

It is planned to issue a program announcement to encourage grant applications that will increase basic and clinical knowledge about the biology of HIV in semen.

### **Background**

Sexual contact with HIV seropositive men is the major route for transmission of HIV type I. Direct exposure to semen is the primary vehicle for spread through sexual contact. There are very few studies which elucidate the factors that determine HIV shedding in the male genital tract, or the infectivity of HIV in semen fractions. Important research areas include the role of antiretroviral therapy; the relationship between the immunobiology of the male genital tract and HIV replication and infectivity, and factors which influence HIV transmission through semen such as genital tract inflammation.

### **Research Goals and Scope**

The goals of this initiative are to: (1) increase the basic and clinical knowledge of the biology of HIV in semen; (2) identify and characterize the source of HIV in semen; (3) identify and characterize factors which influence infectivity and transport of HIV in semen; (4) characterize host immune interactions which affect transmission of infectious HIV in semen; (5) develop therapeutic approaches which alter either transmission or infectivity of HIV in semen; (6) intensify investigator-initiated research; (7) attract new investigators to the field; and (8) increase interdisciplinary research to enhance the scope and effectiveness of research in this area.

## **INITIATIVE TO DEVELOP MRI TECHNOLOGY FOR ASSESSMENT OF IRON**

### **FY 2003 Action**

It is proposed to issue an RFA in cooperation with NIBIB for projects addressing the adaptation of MRI technology to measurement of body iron.

### **Background**

Non-invasive measurements of body and tissue iron are needed in guiding iron-chelating therapy in transfusional iron overload in patients with thalassemia major (Cooley's anemia), sickle cell disease, aplastic and myelodysplastic anemias, and potentially for public health programs of population screening for hereditary hemochromatosis, the most common genetic disease in populations of European ancestry. At present, biomagnetic susceptometry provides the only non-invasive method for measurement of tissue iron stores that has been calibrated, validated and used in clinical studies but the complexity, cost and technical demands of the liquid-helium-cooled superconducting instruments now required have restricted clinical access to the method. A new grant award to the Columbia University Health Sciences Division will support the development of a new generation of instruments that take advantage of modern superconducting materials and computerization. These improvements will result in simpler and lower cost instruments.

MRI, on the other hand, has the potential to provide information on iron concentration, but also additional information (e.g., tissue morphology and functional status) not available with other iron detection methods, such as susceptometry. However, MRI technology requires further research and technical refinement to make it adaptable for this purpose. The dual-field approach for MRI measurement of brain iron offers promise of greater accuracy than the conventional single-field images.

### **Research Goals and Scope**

Research is needed to determine whether MRI techniques can be applied to assessment of total body or liver iron. A reliable method needs to be developed for calibrating and validating iron concentration detected by magnetic resonance imaging. Many technical issues need to be resolved, including the mechanistic contribution of iron in iron-containing materials (e.g. ferritin and hemosiderin) to magnetic resonance relaxation and selection of the optimum measurement field strength. A careful comparison between methods of iron detection needs to be performed, and there may be innovative ways to adapt MRI to iron measurement, such as the development of indicator materials for direct MR measurement of iron concentration.

## **BASIC RESEARCH STUDIES ON BIOLOGY OF THE BLADDER**

### **FY 2003 Action**

A solicitation will be issued to accompany the publication of the Bladder Progress Review Group report to encourage a broad range of investigator-initiated research applications to fulfill recommendations in this report.

### **Background**

The recent NIDDK-sponsored Bladder Progress Review Group (BPRG) developed research recommendations on all areas of bladder research. Recommendations from the BPRG for specific research tools will be addressed in a separate program announcement. The focus of this solicitation will be hypothesis-driven investigator-initiated proposals.

A major theme throughout the BPRG recommendations is the need for the expanding both the scope of research and the number of investigators focusing on basic bladder research if the translational and clinical studies are to expand and have an impact. The report emphasized the importance of encouraging both basic and clinical investigators with a wide range of expertise to consider research questions relevant to bladder function and disease. Basic areas that were identified as relevant include cell biology, genomics and proteomics, cell imaging, protein structure and mechanisms of cell signaling, cell therapies and tissue engineering. Clinical disciplines of relevance include epidemiology and outcomes research, and radiology.

### **Research Goals and Scope**

This solicitation would seek to encourage bladder research by delineating specific areas defined in the Bladder PRG report as areas for investigation, and by encouraging both new (junior) investigators to apply and senior investigators with expertise in related fields to apply their knowledge to specific bladder research areas. Mechanisms supported would include R01 (research project), R21 (exploratory/development project), and IRPG (Interactive Research Project Grant) mechanisms.



**CHRONIC PROSTATITIS COLLABORATIVE RESEARCH NETWORK**  
(RFA DK-03-004) <http://grants.nih.gov/grants/guide/rfa-files/RFA-DK-03-004.html>

**FY 2003 Action**

This initiative will invite cooperative agreement applications for renewal of the Chronic Prostatitis Collaborative Research Network (CPCRN). It is anticipated funding up to ten Clinical Centers to participate in the development and conduct of randomized clinical trials to evaluate novel therapies in patients with chronic prostatitis/Chronic Pelvic Pain Syndrome. A Data Coordinating Center will be established to provide expertise in protocol development including sample size estimation, data analysis, quality control, and data management. The Clinical Centers and the Data Coordinating Center will work together cooperatively to conduct clinical trials sequentially or concurrently.

**Background**

Chronic prostatitis is a disabling condition affecting an untold number of men of all ages and ethnic origins. The majority of patients with chronic prostatitis have chronic pain without any infection of the prostate detectable by conventional microbiological techniques. To date there is no standardized method of diagnosis and treatment of this condition. In 1997, the NIDDK established the Chronic Prostatitis Collaborative Research Network (CPCRN) to conduct epidemiological studies and clinical trials in men with chronic prostatitis. The CPCRN, consisting of ten clinical centers and a data coordinating center, first undertook a prospective cohort study of nearly 500 men. In the summer of 2001, a randomized, controlled clinical trial of an alpha blocker (Flomax) and an antibiotic (Ciprofloxacin) in a two-by-two factorial design was initiated.

Also in 1997, the NIDDK established and funded the Interstitial Cystitis Clinical Trials Group (ICCTG) to plan and conduct randomized, controlled clinical trials of promising therapies for patients with interstitial cystitis. Interstitial cystitis is another chronic pelvic pain disorder associated with bladder frequency and urgency. Two clinical trials have been conducted by the ICCTG; one used oral therapy while the other trial administered treatment intravesically.

Over the course of the ICCTG and the CPCRN it became apparent that there were similar approaches to conduct clinical trials for these two conditions, including development/use of validated symptom indices to measure response to treatment, the need for institutions to become referral centers for these conditions in order to achieve recruitment goals, and challenges to identify novel therapies that allow for rapid accrual of clinical trial participants.

The NIDDK now wishes to build on the work begun by the CPCRN and ICCTG and conduct additional clinical trials, either sequentially or concurrently, over a second five-year period. Thus, investigators responding to this research solicitation are encouraged to submit grant applications to the RFA for the Interstitial Cystitis Clinical Research Network (ICCRN) (RFA DK-03-003). Successful applicants for these RFAs will work together as the Urological Chronic Pelvic Pain Syndromes Collaborative Group with the goals to shorten the period of protocol development for the two clinical trials groups, to collect common information to permit comparisons of the clinical characteristics of these two conditions, to develop clinically relevant

definitions of the urologic chronic pelvic pain syndromes, facilitating decisions on treatments to be evaluated, and to increase the rate of accrual of study participants to these trials.

### **Research Goals and Scope**

- Establish a collaborative group of clinical trial centers with clinical expertise in chronic pelvic pain, clinical pain management, and chronic prostatitis.
- Design randomized, controlled clinical trials to treat the symptoms associated with chronic prostatitis.
- Recruit sufficient numbers of patients with chronic prostatitis/CCPS, including an adequate number of newly diagnosed cases, into these clinical trials.
- Determine if there is a different response to therapy between sub-groups of patients, including newly diagnosed and chronic, long-term patients with the disorder.
- Conduct ancillary studies to improve understanding of the fundamental mechanisms of chronic pelvic pain and chronic prostatitis.

## **CELL TYPE TOOLS FOR PROSTATE AND BLADDER (PAR-02-143)**

<http://grants2.nih.gov/grants/guide/pa-files/PAR-02-143.html>

### **FY 2003 Action**

This Program Announcement will encourage the development of new, cell-selective research tools and methods applicable to studies of the bladder, prostate, and other organs of the GU tract.

### **Background**

The cellular heterogeneity of the bladder, prostate, and other organs of the genitourinary (GU) system creates special challenges for researchers. Resident specialized cells have unique roles in maintaining proper organ structure and function, and hence they are expected to express a distinct complement of genes, proteins, and cellular features. To describe the roles of individual cell types in organ physiology and pathophysiology of disease, investigators must successfully isolate and analyze the cell types for their unique cellular and functional characteristics.

Therefore, the development of tools, reagents, and methods to define the cellular complexity and function of these organs is critical.

The primary goal of this initiative is to promote the development of research tools and innovative methods that may be applied to studies of individual cell types of the bladder, prostate, and GU tract. Elucidating the function of physiologically relevant, specialized cell types will enhance our understanding of the function of these organs under healthy and pathological states. This may in turn aid in the future development of therapeutics for diseases such as interstitial cystitis, infertility, benign prostatic hyperplasia, prostate cancer, and other malignant and non-malignant disorders of the GU tract, as well as in the discovery and development of novel targets for male contraception. Achieving the goals outlined in this PAR is deemed a high-priority by both the Bladder Research Progress Review Group

([http://www.niddk.nih.gov/fund/other/bladderprg\\_web/index.html](http://www.niddk.nih.gov/fund/other/bladderprg_web/index.html)) and the Prostate Research Progress Review Group.

### **Research Goals and Scope**

This PAR is intended to encourage the development of new, cell-specific research tools and methods that may be applied to studies of the bladder, prostate, and other organs of the GU tract. In this solicitation, “selective” indicates restricted to or prominent in certain cell types.

Strategies to be supported include: (1) discovery of genes selective to individual cell types; (2) characterization of cell-selective promoters; (3) generation of transgenic mice carrying gene disruptions under cell-selective or temporal control; (4) generation of antibodies to cell-selective proteins; (5) development of novel imaging techniques to study individual cell types; (6) discovery of biomarkers that indicate health or mass of individual cell types; (7) development of cell-selective “drugable” targets and assays for such targets in animal models and/or humans; and (8) identification of cell-specific markers to aid studies of epithelial-stromal interaction in normal and malignant tissues.

## **DAILY DIALYSIS REGISTRY**

### **FY 2003 Action**

Existing contract mechanisms will be utilized to establish a study to assess the number and characteristics of patients receiving “daily dialysis” in the U.S.

### **Background**

More frequent hemodialysis has been employed by some centers in small numbers of selected patients. The modalities have included home and in-center hemodialysis delivered four to seven times per week with standard blood and dialysate flow rates but usually for shorter duration per dialysis session than with the thrice weekly schedule. Alternatively, lower than standard flow rates have been used but for longer periods of time than the usual, often at night and often more frequently than three times per week. All of the patients currently under some type of more frequent dialysis already are in the USRDS data system. However, they have not been identified as such. There is currently no mechanism to distinguish frequent from three times per week dialysis. With a modest increase in funding to the USRDS, we can identify these persons in our special study populations. Having done so, descriptive and epidemiological studies can be conducted to compare them with conventional dialysis patients. This will give the best information on this potentially important therapy to date. These analyses will also enable NIDDK to more effectively design trials in the future.

### **Research Goals and Scope**

Through the USRDS and in cooperation with CMS, a mechanism will be established to obtain comprehensive reporting of dialysis frequency in all Medicare dialysis reports. Analyses will be performed about the impact of dialysis frequency on patient outcomes. Data will be made available to the community through the Annual Reports and the USRDS data tapes.

## **INTERSTITIAL CYSTITIS CLINICAL TRIALS NETWORK (RFA DK-03-003)**

<http://grants.nih.gov/grants/guide/rfa-files/RFA-DK-03-003.html>

### **FY 2003 Action**

The DKUHD of the NIDDK will invite cooperative agreement applications for renewal of the Interstitial Cystitis Clinical Trial Group (ICCTG). It is anticipated funding up to ten Clinical Centers to participate in the development and conduct of randomized clinical trials to evaluate novel therapies in patients with interstitial cystitis and chronic pelvic pain syndrome. A Data Coordinating Center will be established to provide expertise in protocol development including sample size estimation, data analysis, quality control, and data management. The Clinical Centers and the Data Coordinating Center will work together cooperatively to conduct clinical trials sequentially or concurrently.

### **Background**

Interstitial cystitis is a disabling condition associated with severe pelvic pain, urinary frequency and dysuria. It affects women more often than men, but has been reported in all age groups and both genders. The majority of patients with this disorder have severe urinary tract symptomatology and chronic pain, but there is no standardized method of diagnosis or treatment of this condition.

The NIDDK has a longstanding interest in clinical and epidemiological research for interstitial cystitis. In 1991 the Interstitial Cystitis Database (ICDB) study was initiated. The ICDB Study was a five-year prospective cohort study of over 600 men and women with symptoms of urinary urgency, frequency, and pelvic pain. Reports have described the longitudinal changes of urinary symptoms, the impact of interstitial cystitis on quality of life, treatment patterns and the relationship between findings from bladder biopsies with patient symptoms. As a follow-up to the ICDB Study, the NIDDK issued an RFA in 1997 to establish the Interstitial Cystitis Clinical Trials Group (ICCTG) to plan and conduct randomized controlled clinical trials of promising therapies for patients with interstitial cystitis. Two clinical trials have been conducted by the ICCTG; one used oral therapy while the other trial administered treatment intravesically. Ancillary studies of various biomarkers were developed and conducted in conjunction with this trial. The NIDDK now wishes to build on the work begun by the ICCTG and conduct additional clinical trials, either sequentially or concurrently, over a second five-year period.

### **Research Goals and Scope**

- Establish a collaborative group of clinical trial centers with clinical expertise in chronic pelvic pain, clinical pain management, and interstitial cystitis.
- Design randomized controlled clinical trials to treat the symptoms associated with interstitial cystitis.
- Recruit sufficient numbers of patients with interstitial cystitis, including an adequate number of newly diagnosed cases, into these clinical trials.
- Conduct ancillary studies to provide further understanding of interstitial cystitis.
- Determine if there is a different response to therapy between newly diagnosed and chronic, long-term patients with the disorder.

## **BASIC RESEARCH STUDIES ON INTERSTITIAL CYSTITIS**

### **FY 2003 Action**

A Request for Applications will be issued to encourage and support basic cellular, molecular, and genetic research pertinent to interstitial cystitis (IC) from both new and established investigators in relevant fields of study. Areas of interest include, but are not restricted to, the etiology and pathogenesis of IC; the neurological aspects of IC; and the genetics of IC susceptibility, causality, and disease progression. The hope of the NIDDK is that this initiative will aid future development of reliable IC diagnostic tools and effective disease treatments.

### **Background**

Known as the “painful bladder syndrome”, interstitial cystitis is a debilitating, chronic bladder syndrome that causes urinary urgency and frequency, and severe pain in the bladder and surrounding pelvic region. It has been estimated that IC may affect as many as one million Americans. The disorder has been reported in men, women and children of all ages and races; however, approximately 90 percent of sufferers are women with symptoms typically beginning around the age of 40. Diagnosis of IC is primarily based on symptoms, as there are no currently available blood or urine tests due to the lack of established biological markers. There are no cures or even consistently effective therapies available to treat IC, which remains an idiopathic disorder possibly deriving from multiple causes.

### **Research Goals and Scope**

This initiative is intended to encourage research in this area from both established investigators active in bladder research as well as investigators new to the field. Areas of interest include, but are not restricted to, the etiology and pathogenesis of IC; the neurological aspects of IC; and the genetics of IC susceptibility, causality, and disease progression. Additional topics identified by the Bladder Progress Review Group as germane to progress in interstitial cystitis include study of mechanisms of interaction between neuroendocrine factors and bladder urothelium and smooth muscle, molecular mechanisms of urothelium permeability, identification of urine markers in IC patients, studies of the effect of frequent micturition and other forms of mechanical perturbation on bladder wall components and function, and studies of pelvic pain pathways. Studies will use the R01 (research project), R21 (exploratory/development project), and IRPG (Interactive Research Project Grant) mechanisms for a one-time receipt date anticipated in early 2003 and review and award dates anticipated in late 2003.

## **DIVISION OF KIDNEY, UROLOGIC AND HEMATOLOGIC DISEASES**

### **Conferences and Workshops**

#### **Hepatitis C and Kidney Disease**

**Date: October 20-21, 2002**

This workshop, co-sponsored by the DDN and KUH Divisions, will assess current knowledge about the relationship between hepatitis C virus (HCV) infection and renal disease and current optimal means of prevention, control and treatment of hepatitis C in patients with kidney disease. Hepatitis C is a cause of renal disease and is also a frequent complication during the management of end-stage renal disease. The workshop will be a day-and-a-half meeting that will include oral presentations from 19 national and international speakers on topics of hepatitis C virology, epidemiology, natural history and therapy; incidence of HCV-related renal disease and its natural history; prevalence of HCV infection among patients with end-stage renal disease on dialysis and after renal transplantation; natural history of hepatitis C in patients with renal disease, on dialysis and after transplantation; the problem of renal disease in patients with HCV infection after liver transplantation; prevention of spread of HCV in renal disease patients and therapy of hepatitis C in patients with end-stage renal disease and after renal transplantation. The objective of the meeting is to set a research agenda in the area of hepatitis C and renal disease.

#### **Proteinuria as a Surrogate Marker for Renal Clinical Trials**

**Date: October 2002**

**(Co-sponsored by the National Kidney Foundation)**

The purpose of this workshop is to explore all aspects of use of reduction in proteinuria as an outcome measure in clinical trials of treatments for kidney disease.

#### **Planning a Career in Clinical Investigation in Urology**

**Date: November 2002**

#### **Planning a Career in Clinical Investigation in Nephrology**

**Date: December 2002**

Two meetings will be held for young investigators considering careers in clinical investigation—one for urologists and those interested in urological diseases and one for nephrologists and those interested in kidney diseases. These meetings will use a highly successful format that combines discussion of scientific topics with grantsmanship advice and mock study sections.

#### **Urological Complications of Diabetes**

**Date: Spring 2003**

A workshop will be organized to address the state of research into the urological complications of diabetes, including the impact on urinary tract infections and micturition and male sexual function.

#### **Recruitment and Retention of Minority and Disadvantaged Subjects in Clinical Studies**

**Date: Spring 2003**

**(Co-sponsored by the National Center on Minority Health and Health Disparities)**

This meeting will address the best strategies to ensure appropriate participation of minority subjects and subjects from disadvantaged populations in clinical trials, and will include discussion of ethical aspect, recruitment and retention.

**Interstitial Cystitis—New Directions for Both Basic and Clinical Investigation**

**Date: November 2003**

**(Co-sponsored by the Interstitial Cystitis Association)**

This workshop will address research progress and research needs for interstitial cystitis.

**Cell Fate—Developmental and Stem Cell Perspectives**

**Date: Spring 2003 (Tentative)**

The organization of a workshop is being considered to bring together developmental biologists and investigators with stem cell expertise to promote interdisciplinary interactions between these two communities.

**Pharmacogenetics and Clinical Trials**

**Date: Spring 2003 (Tentative)**

A working group will be established to provide advice about clinical trial populations and their potential utility to establish genetic markers of pharmaco-responses.

**Cardiovascular Disease in Chronic Renal Disease**

**Date: Spring 2003**

This workshop will examine the state of knowledge about the increased cardiovascular risk associated with renal disease, including pathophysiology, prevention and potential research strategies.

**Aging and the Kidney**

**Date: December 2003 (Tentative)**

**(Co-sponsored by the National Institute on Aging)**

This workshop will explore the impact of aging on kidney function and disease and treatment of kidney disease in the elderly.